Mass General Brigham
Health Plan

Radicava (edaravone)
Radicava ORS (edaravone)
Effective 11/01/2022

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Radicava™ (edaravone) is a free radical and peroxynitrite scavenger that prevents oxidative damage to cell membranes and indicated for the treatment of amyotrophic lateral sclerosis (ALS).

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving Radicava excluding when the product is obtained as samples or via manufacturer's patient assistance program.
OR
Authorization may be granted for members with a diagnosis of ALS based on EI Escorial revised criteria when ALL the following criteria are met:

1. Medication is prescribed by a neurologist or physiatrist with expertise in the treatment of ALS.
2. Member is stable on Rilutek (riluzole) or the prescriber has submitted clinical rationale why Rilutek (riluzole) is not appropriate.
3. Member has normal respiratory function defined as percent-predicted forced vital capacity (FVC) values of ≥80%.
4. Member has a score of at least 2 points on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R).
5. Member has had duration of disease for 2 years or less.
6. Member does not require noninvasive or invasive ventilatory support.

<u>Continuation of Therapy</u>
Reauthorization may be granted for members when ALL the following criteria are met:

1. Medication is prescribed by a neurologist or physiatrist with expertise in the treatment of ALS.
2. Documentation confirming the patient has benefitted from Radicava (Edaravone) therapy as demonstrated by a slowing in the decline of functional abilities is submitted.

Limitations

1. Initial approvals will be for 6 months.
2. Reauthorizations will be for 12 months.

References

1. Radicava (edaravone) [prescribing information]. Jersey City, NJ: MT Pharma America Inc; May 2017.
2. Nagase M, Yamamoto Y, Miyazaki Y, Yoshino H. Increased oxidative stress in patients with amyotrophic lateral sclerosis and the effect of edaravone administration. Redox Rep. 2016;21(3):104-112.[PubMed 26191780]
3. Miller RG, Mitchell JD, Moore DH. Riluzole for amyotrophic lateral sclerosis (ALS)/motor neuron disease (MND). Cochrane Database Syst Rev 2012: CD001447
4. [Study of functional rating scale for amyotrophic lateral sclerosis: revised ALSFRS(ALSFRS-R) Japanese version]. No To Shinkei. 2001 Apr;53(4):346-55.
5. Writing Group, Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well-defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo-controlled trial. Lancet Neurol 2017; 16:505.
6. Hardiman O, van den Berg LH. Edaravone: a new treatment for ALS on the horizon? Lancet Neurol 2017; 16:490

Review History

11/26/18 – Reviewed
01/22/20 – Added started & stabilized criteria
09/21/2022 – Reviewed and Updated for Sept P&T; separated out Comm/Exch and MH. Added new formulation Radicava ORS available on the pharmacy benefit ONLY. Effective 11/01/2022